K081916

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.

JUL 22 2008

Submitter: GE Medical Systems, LLC
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Date Prepared: June 5, 2008

Device Name:

Proprietary Name: GE Signa® MR Oncology Package

Common Name: Patient Positioning Accessory for Magnetic Resonance Imaging System

Classification Name: Magnetic Resonance Diagnostic Device, (21 C.F.R. 892.1000, LNH)

Predicate Devices:

GE 1.5T and 3.0T Signa® HDx MR System (K052293)

Device Description:

The GE Signa® MR Oncology Package includes a patient table that can be used with a GE Signa® MR System and MR-compatible patient positioning and immobilization devices. The Signa® Oncology Table is similar to the existing detachable patient table offered with Signa® MR Systems. It utilizes the detachable table system to offer a flat patient surface. The flat surface enables patients to be positioned similar to other diagnostic and therapeutic devices that also utilize flat patient surfaces. Also, the Signa® MR Oncology Package may be used with MR-compatible patient immobilization accessories to assist in consistent patient positions throughout multiple imaging sessions.

Intended Use:

The GE Signa® MR Oncology Package is a patient positioning package intended for use with GE Signa® MR Systems.

The Signa® MR Oncology Package when used with a Signa® MR system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio and short scan times. The Signa® MR system with Signa® MR Oncology Package is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the Signa® MR system with Signa® MR Oncology Package reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.
The Signa® MR Oncology Package provides an additional patient table for Signa® MR systems that allows patients to be imaged on a flat surface. The flat patient surface enables Signa® MR systems to acquire images in patient positions similar to other modalities that also utilize a flat patient surface such as X-Ray, CT, PET, and radiation therapy. The Signa® MR system with Signa® MR Oncology Package may also be used with MR-compatible patient positioning and immobilization accessories to assist in obtaining consistent patient positions throughout multiple imaging sessions.

Comparison with Predicate Devices:

The GE Signa® MR Oncology Package is an accessory for the previously cleared GE 1.5T and 3.0T Signa® HDx MR System and MRI systems utilizing the same removable patient table. The primary difference is a modification to the removable patient table to offer a flat patient surface. The immobilization devices are previously cleared devices (K080072), and are not altered when packaged with the GE Signa® Oncology Table.

Summary of Studies:

The GE Signa® MR Oncology Package has been evaluated to the appropriate clauses of IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety standard. Also, the patient contacting surface has been evaluated using the methodology and appropriate parts of 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing and the related 10993-5 and 10993-10 for Biocompatibility.

The Signa® MR Oncology Package is an accessory for the currently marketed 1.5T and 3.0T Signa® HDx MR System. The modified table has been verified to function with the Signa® HDx MR System. Additionally, clinical image comparisons demonstrate that the Signa® MR Oncology Package maintains the same imaging performance as the Signa® HDx MR System with existing patient table.

Conclusion:

It is the opinion of GE that the GE Signa® MR Oncology Package is substantially equivalent to the currently marketed GE 1.5T and 3.0T Signa® HDx MR System and the patient table used with these systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2008

GE Medical Systems, LLC
% Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K081916
Trade/Device Name: GE Signa® MR Oncology Package
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 3, 2008
Received: July 7, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

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Prescription Use ___X___ **AND/OR** **Over-the-Counter Use** _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081916